

LUPIN LIMITED

SAFETY DATA SHEET

Section 1: Identification

Section 1, Identification

Material	Budesonide Inhalation Suspension 0.5 mg/2 mL
Manufacturer	The Ritedose Corporation 1, Technology Circle, Columbia, South Carolina 29203 United States Tel. 001-803-935-4196 Fax. 001-803-935-4686
Distributor	Lupin Pharmaceuticals, Inc. 111 South Calvert Street, Harborplace Tower, 21st Floor, Baltimore, Maryland 21202 United States Tel. 001-410-576-2000 Fax. 001-410-576-2221

Section 2: Hazard(s) Identification

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Fire and Explosion	Expected to be non-combustible.
Health	The use of budesonide inhalation suspension is contraindicated in the following conditions: <ul style="list-style-type: none">• Primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.• Hypersensitivity to budesonide or any of the ingredients of budesonide inhalation suspension
Environment	No information is available about the potential of this product to produce adverse environmental effects.

Section 3: Composition/Information on Ingredients

Section 3, Composition/information on ingredients

Ingredients	CAS
Budesonide USP	51333-22-3

Section 4: First-Aid Measures

Section 4, First-aid measures

Ingestion	Flush out mouth with water, consult a physician immediately.
Inhalation	In case of inhalation remove to fresh air and seek medical aid.
Skin Contact	Remove immediately contaminated clothes, wash affected skin with plenty of water.
Eye Contact	In case of contact with eyes rinse thoroughly with plenty of water and get medical advice.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center. Protect the patient's airway and support ventilation and perfusion. Meticulously monitor and maintain, within acceptable limits, the patient's vital signs, blood gases, serum electrolytes, etc.
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OVERDOSAGE

The potential for acute toxic effects following overdose of budesonide inhalation suspension is low. If inhaled corticosteroids are used at excessive doses for prolonged periods, systemic corticosteroid effects such as hypercorticism or growth suppression may occur.

In mice, the minimal lethal inhalation dose was 100 mg/kg (approximately 410 and 120 times, respectively, the maximum recommended daily inhalation dose in adults and children 12 months to 8 years of age on a mg/m² basis). In rats there were no deaths at an inhalation dose of 68 mg/kg (approximately 550 and 160 times, respectively, the maximum recommended daily inhalation dose in adults and children 12 months to 8 years of age on a mg/m² basis). In mice, the minimal oral lethal dose was 200 mg/kg (approximately 810 and 240 times, respectively, the maximum recommended daily inhalation dose in adults and children 12 months to 8 years of age on a mg/m² basis). In rats, the minimal oral lethal dose was less than 100 mg/kg (approximately 810 and 240 times, respectively, the maximum recommended daily inhalation dose in adults or and children 12 months to 8 years of age on a mg/m² basis).

Section 5: Fire-Fighting Measures

Section 5, Fire-fighting measures

Fire and Explosion Hazards	Assume that this product is capable of sustaining combustion.
Extinguishing Media	Use extinguishing media appropriate to surrounding fire conditions, such as water, fog, spray, dry chemical, regular foam, carbon dioxide.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapors might be evolved from fires involving this product and associated packaging, self-contained breathing apparatus and full protective equipment are recommended for firefighters.

Hazardous Combustion Products

Hazardous combustion or decomposition products are expected when the product is exposed to fire.

Section 6: Accidental Release Measures

Section 6, Accidental release measures**Personal Precautions**

Avoid excessive contact and contact with eyes. Wear safety goggles or shield.

Environmental Precautions

For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

Clean-up Methods

This material is not known to possess additional hazards when spilled beyond those of other non-hazardous solids.

Section 7: Handling and Storage

Section 7, Handling and storage**Handling**

No special control measures required for the normal handling of this product.

Storage

Budesonide inhalation suspension should be stored upright at controlled room temperature 20 to 25°C (68 to 77°F) [see USP], and protected from light.

When an envelope has been opened, the shelf life of the unused ampules is 2 weeks when protected. After opening the aluminum foil envelope, the unused ampules should be returned to the aluminum foil envelope to protect them from light. Any opened ampule must be used promptly. Gently shake the ampule using a circular motion before use. Keep out of reach of children. Do not freeze.

Section 8: Exposure Controls/Personal Protection

Section 8, Exposure controls/personal protection

Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

Section 9: Physical and Chemical Properties

Section 9, Physical and chemical properties**Physical Form**

Budesonide inhalation suspension is supplied in sealed aluminum foil envelopes containing one plastic strip of five single-dose ampules together with patient instructions for use. There are 30 ampules in a carton. Each single-dose ampule contains 2 mL of white to off-white sterile liquid suspension.

Budesonide inhalation suspension is available in single strength, containing 2 mL :

Section 10: Stability and Reactivity

Section 10, Stability and reactivity

Stable under recommended storage conditions.

Section 11: Toxicological Information

Section 11, Toxicological information

Carcinogenesis, Mutagenesis, Impairment of Fertility

In a two-year study in Sprague-Dawley rats, budesonide caused a statistically significant increase in the incidence of gliomas in male rats at an oral dose of 50 mcg/kg (approximately 0.4 and 0.1 times, respectively, the maximum recommended daily inhalation dose in adults and children 12 months to 8 years of age on a mcg/m² basis). No tumorigenicity was seen in male rats at oral doses up to 25 mcg/kg (approximately 0.2 and 0.06 times, respectively, the maximum recommended daily inhalation dose in adults and children 12 months to 8 years of age on a mcg/m² basis) and in female rats at oral doses up to 50 mcg/kg (approximately 0.4 and 0.1 times, respectively, the maximum recommended daily inhalation dose in adults and children 12 months to 8 years of age on a mcg/m² basis). In two additional two-year studies in male Fischer and Sprague-Dawley rats, budesonide caused no gliomas at an oral dose of 50 mcg/kg (approximately 0.4 and 0.1 times, respectively, the maximum recommended daily inhalation dose in adults and children 12 months to 8 years of age on a mcg/m² basis). However, in the male Sprague-Dawley rats, budesonide caused a statistically significant increase in the incidence of hepatocellular tumors at an oral dose of 50 mcg/kg (approximately 0.4 and 0.1 times, respectively, the maximum recommended daily inhalation dose in adults and children 12 months to 8 years of age on a mcg/m² basis). The concurrent reference corticosteroids (prednisolone and triamcinolone acetonide) in these two studies showed similar findings.

In a 91-week study in mice, budesonide caused no treatment-related carcinogenicity at oral doses up to 200 mcg/kg (approximately 0.8 and 0.2 times, respectively, the maximum recommended daily inhalation dose in adults and children 12 months to 8 years of age on a mcg/m² basis).

Budesonide was not mutagenic or clastogenic in six different test systems: Ames *Salmonella* microsome plate test, mouse micronucleus test, mouse lymphoma test, chromosome aberration test in human lymphocytes, sex-linked recessive lethal test in *Drosophila melanogaster*, and DNA repair analysis in rat hepatocyte culture.

In rats, budesonide had no effect on fertility at subcutaneous doses up to 80 mcg/kg approximately 0.6 times the maximum recommended daily inhalation dose in adults on a mcg/m² basis. However, it caused

a decrease in prenatal viability and viability in the pups at birth and during lactation, along with a decrease in maternal body-weight gain, at subcutaneous doses of 20 mcg/kg and above approximately 0.2 times than the maximum recommended daily inhalation dose in adults on a mcg/m² basis. No such effects were noted at 5 mcg/kg (approximately 0.04 times the maximum recommended daily inhalation dose in adults on a mcg/m² basis).

Section 12: Ecological Information

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No relevant studies identified.

Section 13: Disposal Considerations

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Incinerate in an approved facility. Follow all federal state and local environmental regulations.

Section 14: Transport Information

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IATA/ICAO - Not Regulated

IATA Proper shipping Name	:	N/A
IATA UN/ID No	:	N/A
IATA Hazard Class	:	N/A
IATA Packaging Group	:	N/A
IATA Label	:	N/A

IMDG - Not Regulated

IMDG Proper shipping Name	:	N/A
IMDG UN/ID No	:	N/A
IMDG Hazard Class	:	N/A
IMDG Flash Point	:	N/A
IMDG Label	:	N/A

DOT - Not Regulated

DOT Proper shipping Name	:	N/A
DOT UN/ID No	:	N/A
DOT Hazard Class	:	N/A
DOT Flash Point	:	N/A
DOT Packing Group	:	N/A
DOT Label	:	N/A

Section 15: Regulatory Information

Section 15: Regulatory Information

This Section Contains Information relevant to compliance with other Federal and/or state laws.

Section 16: Other Information

Section 16, Other information

The above information is believed to be correct but does not purport to be all-inclusive and shall be used only as a guide. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

Lupin shall not be held liable for any damage resulting from handling or from contact with the above product. Lupin reserves the right to revise this SDS.